REMARKS

Claims 11, 16-18, and 20-46 were pending.

Claim 11 has been amended to include the language "that is" before the word "incorporated", and has also been amended to add the limitation that the composition contains less than about 5% by weight water. Support for this amendment can be found throughout the disclosure, *e.g.*, page 8, lines 23-34 and pending claim 28 (which has accordingly been canceled without prejudice).

Claim 16 has been amended to end with a period, as required by the Examiner.

Applicants are grateful for the indication in the Office Action that all previous rejections have been withdrawn.

Claims 11, 16-18, 20-28 and 29-46 are now pending.

I.   Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 22 has been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. This claim has been amended to depend from claim 20. or this claim amendment can be found throughout the present disclosure, *e.g.*, in the Specification, at page 5, lines 32-35. Therefore, no new matter has been added.

Applicants respectfully submit that in light of the amendment of claim 22, this rejection has been overcome and should be withdrawn.

II.   Rejections Under 35 U.S.C. § 103(a) Based on Gebreselassie and Wagenknecht

Claims 11, 16-18, 20-24, 26-42 and 44-46 have been rejected under 35 U.S.C. § 103(a) as obvious based on United States Patent No. 6,379,654 to Gebreselassie et al. ("Gebreselassie") in view of U.S. Patent No. 4,148,872 to Wagenknecht et al. ("Wagenknecht"). Applicants respectfully traverse this rejection on the grounds that a prima facie case of obviousness has not been established.

First, there is no motivation to combine the teachings of Gebreselassie and Wagenknecht to arrive at the presently claimed invention. Gebreselassie teaches that paste or gel dentifrice compositions containing an enzyme are useful in providing benefits to teeth. The Office Action acknowledges that Gebreselassie is silent with regard to incorporating such ingredients into confectionary compositions. Wagenknecht teaches a chewing gum for delivery of plaque inhibiting compositions to

the oral cavity. Accordingly, the Office Action asserts that it would have been obvious to combine the teachings of the two references by formulating the enzyme-containing paste or gel dentifrices taught by Gebreselassie in the form of chewing gums as taught by Wagenknecht.

However, Applicants respectfully submit that there is no motivation to combine the teachings as asserted in the Office Action. Gebreselassie teaches that proteolytic enzymes are known to be unstable in a dentifrice environment via inactivation by metal impurities and oxidation (Gebreselassie, col. 5, lines 1-15). The compositions taught by Gebreselassie accordingly contain enzyme stabilizing agents. Furthermore, the highly stable formulations taught by the reference are in the form of pastes or gels, which all contain at least about 15% water (see, e.g., Gebreselassie, Tables I-VI). Gebreselassie teaches that such enzyme compositions exhibit maximum lipolytic activity in the pH range of 5 to 7 (Gebreselassie, col. 3, lines 24-25). Therefore, a skilled artisan would expect, based on Gebreselassie, that enzyme-containing oral care formulas could be stabilized by the presence of enzyme stabilizing agents in an inert and stable paste or gel form (i.e., containing certain levels of water to create environments in the optimal pH range in order to create a stable formulation with maximum activity).

In contrast, Wagenknecht teaches tablet formulations containing small amounts of water (as low as 2%). Thus, there is no teaching or suggestion in Wagenknecht that such a formulation would successfully stabilize an enzyme. With such low levels of water, one of ordinary skill in the art would not be motivated to optimize pH in order to stabilize and optimize such formulations. Hence, there is no motivation to combine Gebreselassie (which teaches stable paste or gel formulations with an enzyme stabilizing agent and certain level of water to provide a certain pH range for stabilizing and optimizing enzymes) with Wagenknecht (which teaches tablet formulations with low levels of water and therefore is not concerned with stabilization of enzymes) to arrive at the presently claimed invention.

Even if there were a motivation to combine the two references, there would be no expectation of success as a result. One of ordinary skill in the art would expect, upon viewing the two references in combination, that it would be impossible to incorporate an enzyme into a confectionary composition, because the optimal pH value could not be achieved in the manner taught by Wagenknecht in a chewing gum formulation versus a

paste or gel formulation. Primarily, Because Gebreselassie teaches that the optimal pH range is 5 to 7, a skilled artisan would expect that a combination of the two references would yield a composition with extremely unstable enzyme activity, that would therefore be ineffective at delivering antiplaque activity to the oral cavity. At best, the yielded product would be an enzyme containing compound where the enzyme is highly unstable, because the amounts of water present would be insufficient to create an optimal pH range. Even if the water amount were then increased to the levels taught by Gebreselassie in order to maximize the enzyme's stability and performance, the resultant composition would have a paste or gel consistency and thus fail as a chewing gum.

The present invention points out the importance of minimizing water content in chewable confectionary compositions (Specification, page 8, line 23 to page 9, line 3). Therefore, as shown, the presently claimed invention provides an unexpectedly stable formulation in chewable confectionary form in the presence of a minimum of water. Such a composition is clearly not obvious in view of the cited. For at least these reasons, Applicants respectfully submit that this rejection has been overcome, and request that it be withdrawn.

III.   Rejections Under 35 U.S.C. § 103(a) Based on Gebreselassie, Wagenknecht and
         Andersen

Claims 25 and 43 have been rejected under 35 U.S.C. § 103(a) as being obvious based on Gebreselassie in view of Wagenknecht and further in view of U.S. Patent No. 5,487,902 to Andersen et al. ("Andersen"). Applicants respectfully traverse.

Claims 25 and 43 are not obvious in view of a combination of the above-identified references, because, *inter alia*, they are both dependent from claim 11, which is patentable over Gebreselassie and Wagenknecht for the reasons stated above. Furthermore, the addition of Andersen still does not render these claims obvious.

The Office Action states that Andersen "teaches that it is well-known to vary the type and proportions of such ingredients depending on the desired properties of the final chewing gum product." (Office Action, p. 6). However, where as here, Gebreselassie teaches pastes and gels with a higher water content than the chewing gums of Wagenknecht, it would not have been obvious to vary the amount of water in

such amounts in order to incorporate an effectively stabilize and optimize enzymes, while still retaining a low water concentration, as recited in present claims 25 and 43. Thus, claims 25 and 43 are not obvious in view of a combination of the teachings of the three references. Accordingly, Applicants respectfully submit that this rejection has been overcome and should be withdrawn.

In view of the above amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance, early notice of which is earnestly solicited. Should any outstanding issues remain, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number below.

No fee is believed to be due for the filing of this *Amendment and Response*. However, the Director is hereby authorized to charge any fees due to Deposit Account No. 03-2455.

Respectfully submitted,

Du-Thumm *et al.*

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By: Rachel J. Lin
Reg. No. 51,098
COLGATE-PALMOLIVE COMPANY
909 River Road; P.O. Box 1343
Piscataway, NJ 08855-1343
Telephone (732) 878-7993

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